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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,131

11/01/2003

Martin T. Gerber

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EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

07/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,131	<b>Applicant(s)</b> GERBER ET AL.	
	<b>Examiner</b> John P. Lacyk	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 20, 21 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 20, 21 and 26-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

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|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 15-16, 20-21, 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (6,338,345) in view of Goupil (6,652,883).

Johnson et al discloses a device used to deliver a bulking prosthesis to the body.

Johnson et al teaches using an endoscope having a opening (58) or cavity for receiving tissue from the target site, the tissue is drawn into the opening by a vacuum and a needle is used to make a hole or puncture in the tissue and a "pushing agent" to push the prosthesis from the distal end of the tube through the hole. With respect to the bulking prosthesis Johnson et al teaches (column 16, lines 1-21) that it is well known to use a hydrophilic/hydrogel material as the bulking prosthesis. Also Johnson et al teaches (column 6, line 34-column 7, line 18) that the bulking prosthesis can take on a wide variety of shapes and sizes and that optimal dimensions are patient specific and can be determined through routine experimentation of one skilled in the art.

Johnson et al discloses a device for treating gastroesophageal reflux disease (GERD) and discloses the claimed device and method except for specifically teaching using the bulking prosthesis for treating urinary incontinence. Goupil et al teaches that it is well known to use a bulking material to treat a variety of problems including GERD and urinary incontinence. Therefore a modification of Johnson et al such that the

bulking prosthesis is used to treat urinary incontinence would have been obvious in view of Goupil et al which shows that it is well known to treat both with a bulking prosthesis.

With respect to claims 20-21 and 26-32, Johnson does teach that it is know to use more than one prosthesis as needed (See Figures 1-2, column 5, lines 16-20 and column 6, lines 10-21 with respect to element 16).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al and Goupil in view of Durgin (6,591,838).

Johnson et al discloses the claimed device except for the device includes a radiopaque material. Durgin discloses a bulking prothesis and teaches that it is well known to use radiopaque materials such that the prothesis is capable of being detected in the body. Therefore a modification of Johnson et al such that the prosthesis include a radiopaque material would have been obvious in view of the teachings of Durgin since this would allow the prosthesis to be viewed while inside the body to allow for proper placement and/or make sure the prosthesis does not move from its position.

Applicant's arguments filed 3/25/08 have been fully considered but they are not persuasive. Applicant argues that there would have been "no apparent reason to combine the teachings of Johnson and Goupil and use the Johnson device for treating incontinence and that the size of the Johnson device would not be capable of being used for incontinence. As discussed previously, Johnson et al discloses a bulking device that is used to treat GERD. Goupil discloses that it is well known to use a

bulking material to treat both GERD and urinary incontinence. Therefore one skilled in the art would clearly be motivated to modify the device of Johnson et al such that it could be used to also treat urinary incontinence in view of the teachings of Goupil that show it is known to use a bulking material to treat both and Johnson et al teaches a device for implanting a bulking material into the body and there would have been a reasonable expectation of success. Further the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Goupil would have clearly suggested that since it is well known to use a bulking material to treat both GERD and urinary incontinence that it would have been obvious to one skilled in the art to modify the size of a device used to treat GERD such that it would be sized to treat urinary incontinence. Further the courts have shown that a change in size is an obvious modification.

Applicant argues that Johnson et al does not teach the shape being a partial cylinder having an inner radius sized to conform to the urethra, as pointed out in the rejection Johnson et al teaches that a wide variety of shapes and sizes that are determined by routine experimentation and are not limited to those specifically listed. Since it is known to use a variety of shapes this is considered to include a partial cylinder depending on the particular shape that is best for the intended use of the

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device and in view of Goupil would have been obvious to one skilled in the art. Further Johnson et al discloses one of the many shapes Johnson et al does teach is a "toric" shape, which is defined as a convex semicircular cross section which would appear to be a "partial cylinder" shape or generally a "C" shape. Applicant further states that a "torus" is defined by a doughnut-like ring shape that is formed by revolving a circle about an axis coplanar with the circle that does not intersect the circle, however the examiner must read the claims in the broadest interpretation and also use the broadest interpretation of the terms. As such the dictionary definition of toric or torus would include a large semicircular convex cross section which as stated above would be a generally C-shaped configuration.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/  
Primary Examiner, Art Unit 3735